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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,054	12/07/1998	AUDREY GODDARD	P1154R2	2403

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EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	18

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 28-30, 48-50 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 28-30, 48-50 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6, 13
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-421-632/

Part III: Detailed Office Action

Claims 28-30 and 48-50 are pending and under consideration.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The information disclosure statement filed 9/15/00 has been considered. References 10-12 have not been considered, because they are merely sequences, without any further information or explanation of relevance, and the relevancy of such cannot be assessed in the absence of an alignment with the protein to which the claimed antibodies bind. Similarly, references 4-9 of paper #13 have not been considered.

9/13/02

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 28-30 and 48-50 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The claims are drawn to antibodies that specifically bind to the protein identified as PRO 285, which may block recognition of a Gram-negative or Gram-positive organism by PRO 285 (as recited in claim 30). the specification discloses that the present invention provides newly identified and isolated human Toll polypeptides and antibodies thereto, and that the Toll polypeptides shows significant homology to proteins that have been identified as human toll-like receptors (it is noted that Toll polypeptide and Toll receptor are used interchangeably in the specification). At page 16

it is asserted that the proteins "may be involved in inflammation, septic shock and response to pathogens, and play possible roles in diverse medical conditions...such as, for example, diabetes, ALS, cancer, rheumatoid arthritis, and ulcers. The role of PRO285, PRO286 and PRO385 as pathogen pattern recognition receptors, sensing the presence of conserved molecular structures present on microbes, is further supported by the data disclosed in the present application, showing that a known human Toll-like receptor, TLR2, is a direct mediator of LPS signaling." Thus, the specification asserts that the claimed antibodies have diagnostic use, and further that they can be used to interfere with binding of PRO285 to bacterial cells. At page 36 the specification further asserts the use of the antibodies for diagnostic assays, and at page 37 line 2, for purification of PTO285.

While the asserted utilities with respect to preventing bacterial binding or use in diagnosis are specific and substantial, they would not be considered to be credible by the skilled artisan. These utilities are predicted based upon predicted properties of anti-TLR2 antibodies, on the basis that PRO285 shares (an unspecified amount) of homology with TLR2. This is not a credible assertion of utility. The assertion that anti-PRO285 antibodies can be used for the same purposes as anti-TLR2 antibodies would not be considered credible by one of skill in the art because such utilities have not been credibly established for TLR2, nor, even if they were, would such be predictive of homologous proteins such as PRO285. It is noted that when the sequence of PRO285 was searched against all available databases, that no significant homology to TLR2 was detected. Therefore, it would not be predictable that the two proteins, and hence antibodies that bind such, would share any specific structure or function. There is no disclosure of any disease with which PRO285 itself is correlated, nor any bacterium to which it binds. Finally, use of the claimed antibodies for isolation of PRO285 polypeptides, while specific, is not substantial, as any antibody may be used to isolate its cognate antigen; to confer utility to the antibody, the isolation has to have utility. In this case, the only reason for binding PRO285 is for the purpose of learning more about the protein itself, that is, for further research into the properties and characteristics of the protein, which is insufficient to meet the requirement of 35 U.S.C. § 101.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentech, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification provides the sequence of a protein, and then goes on to invite the reader to find out what the biological significance of the protein is, with suggestions as to what 'might' be. There is not credible correlation of the protein with any real world, available use, nor, by extension is there any real world use for the claimed antibodies. The instant specification lacks utility and is not enabling because one cannot, following the guidance presented therein, practice the suggested method without first making a substantial inventive contribution.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-30 and 48-50 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite as it is not clear that SEQ ID NO: 2 exactly corresponds to "DNA40021" over the entirety of both sequences. Amendment of the claim to (a) remove the parentheses and (b) delete reference to DNA 40021 would be remedial.

Claims 29 and 30 are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruggeri et al., WO 91/09614.

Ruggeri et al. disclose a 19 residue peptide that matches the protein encoded by SEQ ID NO: 2 at positions 704-712, a 9/15 match; see the third peptide listed in claim 1. At page 19 and in claim 65, antibodies to such peptides are disclosed and claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al., WO 91/09614, in view of Coughlin, U.S. Patent Number 5,256,766.

The claims differ from those rejected under 35 U.S.C. § 102(b) above in that they recite that the antibody is a monoclonal antibody.

The teachings of Ruggeri et al. are summarized above. Ruggeri et al. do not teach monoclonal antibodies.

The production of monoclonal antibodies and cells that make them is notoriously old in the art. For example, Coughlin teaches recombinant thrombin receptor and antibodies thereto. Columns 11-12 teach the production of polyclonal and monoclonal antibodies, including hybridoma cells producing the monoclonal antibodies. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to make hybridoma cells and monoclonal antibodies as taught by Coughlin reactive with the peptide of Ruggeri. The person of ordinary skill in the art would have been motivated to do so to attain the known and expected advantages of monoclonal antibodies, viz. ease of production and purification.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al., WO

91/09614, in view of Coughlin, U.S. Patent Number 5,256,766, and further in view of U.S. Patent Number 4,946,778 (Ladner et al.) .

Ladner et al. teach the construction of single chain antibodies. The stated advantages of such single chain antibodies as enumerated at column 3 lines 32-48 include smaller size, greater stability, lower cost, lower immunogenicity, etc.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to make monoclonal antibodies as taught by Coughlin et al. to the peptides of Ruggeri et al., and then generate single chain antibodies as taught by Ladner et al. to attain the known and expected advantages of such as set forth by the secondary reference and as referred to above. It is noted that a single chain antibody is considered to meet the limitation of being a 'chimeric antibody', as claimed in claim 50.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner

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9/12/02